

REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed December 28, 2006 ("Office Action"). Claims 1, 27 and 30-35 are pending in the application. Support for the amended claims may be found for example at page 3, lines 8-10 and page 5, line 5, and additionally by way of the original claims. Specifically, support for the particle size range in the pending claims may be found, for example, at page 5, lines 11-12, of the originally filed specification. Applicant respectfully requests reconsideration of the rejection of the pending claims.

Obviousness -- 35 U.S.C. § 103

The Office Action rejects claims 1, 3-5, 8, and 27-29 under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,512,491 ("Mehkeri") and the specification page 5, lines 7-8.

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." Manual of Patent Examining Procedure § 2143.03 (8th ed., rev. 2, May 2004). "When evidence of secondary considerations such as unexpected results is initially before the Office, for example in the specification, that evidence should be considered in deciding whether there is a prima facie case of obviousness." M.P.E.P. § 2144.08.

The Mehkeri Reference

Mehkeri discloses ultra-trace level analysis of water using a coated CELITE (a diatomaceous earth product) support material. Mehkeri, col. 4, ll. 58-67. Mehkeri also discloses that "[s]uitable supports include zeolites, kieselgur, fuller's or diatomaceous earth, alumina and silica gel." Mehkeri, col. 3, ll. 9-12. Mehkeri teaches ultra-trace analysis of water for heavy metals, hydrophobic organic substances, insoluble hydroxide of heavy metals, bacterial, protozoa, diatoms, and other microbia including *Cryptosporidium*. Mehkeri, col. 3, ll. 53-67; col. 11, ll. 7-15. Mehkeri teaches that the diatomaceous earth support should be coated with a "freshly prepared aluminum hydroxide" in order to add hydroxyl groups that will form bonds

with the hydroxyl-bridges found within colloidal carriers. Mehkeri, col. 3, ll. 4-5 and 8-10. Mehkeri further teaches that its trapping media irreversibly fixes colloids to the trapping media to a degree not present with adsorbers. Mehkeri, col. 11, ll. 2-4.

The Examiner correctly recognizes certain differences between the claimed invention and the cited prior art. Claim 1 of this application states:

A method for the removal of *Cryptosporidium* from water comprising the steps of contacting the water with a medium consisting essentially of particulate alumina having a diameter in the range of about 0.5 mm to about 1.5 mm, which alumina contains surface Al-OH groups occurring at an average rate of 1 hydroxyl group per 0.25 nm² to 1 hydroxyl group per 0.18 nm² surface area, for a time from 5 seconds to 1 hour so as to effect at least a 1 log reduction of *Cryptosporidium* present in the water by adsorption thereof onto said alumina.

Applicants are in agreement with the Examiner that Mehkeri fails to teach at least (1) the particle size of the alumina and (2) the surface density of the Al-OH groups. In addition, the Office Action fails to make out a prima facie case of obviousness due to the lack of teaching or suggestion of “a medium consisting essentially of particulate alumina having a diameter in the range of about 0.5 mm to about 1.5 mm” in the cited prior art.

The Secondary Teaching Relied on by the Examiner

At page 2 of the Office Action, the Examiner asserts that “[a]pplicant has admitted that ‘alumina is readily available in different diameter size ranges for example, from about 15 mm down to about 50 microns’ (see page 5, lines 7-8 of the specification).” Office Action, page 2. Applicant would point out, however, that the Office Action fails to point to anything in the asserted prior art that would have led a person of ordinary skill in the art to utilize a medium consisting essentially of particulate alumina having a diameter in the range of about 0.5 mm to about 1.5 mm, much less to utilize the claimed medium in a process that would remove *Cryptosporidium* in the manner required by the claims. Mehkeri utilizes CELITE, a diatomaceous earth (DE), which has a biologically determined particle size that is much lower than the particle size required by the claims. See Appendix E, Fig. 3 (less than 0.064 mm) and Appendix F (0.014 mm). The Office Action fails to present any line of reasoning as to why a person of ordinary skill in the art would employ a particle size range different than that of

Mehkeri and relies solely on the fact that alumina was readily available in different diameter size ranges at the time of the invention to meet the claimed particulate range.

A Medium Consisting Essentially of Alumina

The claimed invention differs from Mehkeri in that it requires, among other limitations, "a medium consisting essentially of particulate alumina having a diameter in the range of about 0.5 mm to about 1.5 mm." The transitional phrase consisting essentially of in the claims makes clear that the particulate alumina has sufficient particle diameter in the range of about 0.5 mm to about 1.5 mm so as to be effective for removal of *Cryptosporidium*.

Mehkeri discloses, at column 3, that the trapping medium may comprise a variety of microporous materials that present "active" hydroxyl groups over the surface of such material. The process of coating in Mehkeri is accomplished by providing CELITE as a support "upon whose surfaces have been deposited, preferably, a thin layer of freshly-prepared aluminum hydroxide" or alternatively magnesium or iron hydroxide. Mehkeri, col. 3, ll. 7-19 and col. 4, ll. 61-64, Table. A person skilled in the art would not have expected the various $Al_x(OH)_y$ forms present in a freshly prepared aluminum hydroxide gel to be the same as the surface of a (solid) hydrated alumina particle. This is because the solid particle (of the present invention) has $Al(OH)$ groups with only one hydroxyl per Al or less. By comparison, the gel layer produced by a coating of freshly prepared aluminum hydroxide will have many $Al(OH)_x$ groups where $x > 1$. Also, the freshly prepared gel will be uneven and weak and the $Al(OH)_x$ groups can more easily shear off, perhaps even with some of the coating material. Thus, a person of ordinary skill in the art would not view the medium of Mehkeri as consisting essentially of particulate alumina.

A person of ordinary skill in the art would not have been motivated to forego the gel coating of Mehkeri to prepare a medium consisting essentially of particulate alumina. The trapping media of Mehkeri is designed to interact with the colloidal carriers which contain the analytes of interest rather than directly trapping the analytes themselves. Moreover, Mehkeri repeatedly disparages the use of adsorbers and actually states that they perform poorly as filters. See Mehkeri, col. 2, ll. 7-31, col. 11, ll. 2-4. In contrast, the medium of the claimed invention has no gel coating, is hydrated, and has a surface density of Al-OH groups that directly removes *Cryptosporidium*. "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,

suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” M.P.E.P. § 2143.01.I. Furthermore, “[i]t is improper to combine references where the references teach away from their combination.” See M.P.E.P. § 2145.X.D (*quoting In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)). The Office Action has failed to state a reason, motivation or suggestion for removing the gel coating taught by Mehkeri and failed to recognize that Mehkeri actually teaches away from the claimed invention. Accordingly, the rejection of under 35 U.S.C. § 103 for obvious over Mehkeri in view of the specification page 5, lines 7-8 is improper and must be withdrawn.

Particle Sizes in the Range of About 0.5 mm to about 1.5 mm

The claims also differ from Mehkeri in that they require, among other limitations, “a medium consisting essentially of particulate alumina having a diameter in the range of about 0.5 mm to about 1.5 mm.” Mehkeri is silent as to the particle size of the materials used. However, Mehkeri utilizes CELITE, a diatomaceous earth (DE), which has a biologically determined particle size that is much lower than the particle size required by the claims. See Appendix E, Fig. 3 (less than 0.064 mm) and Appendix F (0.014mm). Specifically, the claims require a particle size range of about 0.5 mm to about 1.5 mm (about 500 to about 1500 microns), which is not met by the much smaller CELITE particles. Thus, the claims differ from Merkeri by requiring a larger particle size than is present in the disclosure of Mehkeri.

The Examiner recognizes the particle sizes as a difference between the claims and the disclosure of Mehkeri, but nevertheless maintains that a medium having the claimed particle size would have been obvious since such alumina was “readily available.” This rationale for finding obviousness is deficient in that it fails to consider the claimed invention as a whole, which is a method for removing *Cryptosporidium*, and instead focuses on a single element. The Patent Office must show more than the fact that individual elements of the claimed invention can be found in the prior art to render a claim obvious. Moreover, Absent any indication to the contrary, a person of ordinary skill in the art would substitute the particles of alumina having a particle size that is on the same order of magnitude as the particle size of CELITE (which is on the order of 5-20 microns). Thus, to meet the claims one would have to modify Mehkeri by using a particle size for alumina that is more than an order of magnitude larger than the particles

of CELITE that Mehkeri actually used. As recognized by the examiner, “one of ordinary skill in the adsorption art would recognize that a given volume of particles having a smaller diameter would produce more surface area, for adsorption of contaminants, than would the same volume of particles having a larger diameter.” Advisory Action II, page 2. Indeed, it is well known that for spheres “[t]he specific surface area, s , is primarily related to the size of the particles and to some extent the shape of the particles. For spheres it is equal to six divided by the diameter.” Appendix E, page 48, first full paragraph of column 2. Thus, a person of ordinary skill in the art would thus have had no motivation or reasonable expectation that increasing the particle size of the support material of Mehkeri would lead to any improvement in ultra-trace level analysis of water. The Office Action therefore fails to establish a prima facie case of obviousness under 35 U.S.C. § 103 over Mehkeri in view of the specification page 5, lines 7-8.

Removal of *Cryptosporidium* with Hydrated Alumina

Although Mehkeri states that CELITE is moderately directly effective, it does not state that alumina is effective without coating. Moreover, Mehkeri suggests that alumina will perform in a superior manner only if coated with aluminum hydroxide. Mehkeri teaches that CELITE in particular will trap bacteria and protozoa (including *Cryptosporidium*), Mehkeri, col. 11, ll. 8-15, but fails to teach doing so with hydrated alumina as claimed. Finally, Mehkeri treats alumina identically with silica and thus fails to recognize the benefits of using *hydrated* alumina to remove *Cryptosporidium* from water as claimed.

The Office Action recognizes certain differences between the claims and the teachings of Mehkeri, but concludes that it would have been obvious to modify Mehkeri to “dispense with the additional aluminum hydroxide coating suggested by the reference, and to contact the water undergoing treatment directly with the surface of the hydrated alumina, if one were willing to forgo the advantages associated with this additional coating.” Office Action, page 3. This reasoning fails to set forth a prima facie case of obviousness because the Office Action never gives a reason why a person of ordinary skill in the art at the time of the invention would be “willing to forgo the advantages associated with this additional coating.” “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of

ordinary skill in the art.” M.P.E.P. § 2143.01.I. Furthermore, the teachings of Mehkeri run counter to the claimed invention by stating that a coating of material should be used rather than the uncoated support material. “It is improper to combine references where the references teach away from their combination.” See M.P.E.P. § 2145.X.D (*quoting In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)). Finally, merely using the uncoated alumina support in Mehkeri does not meet the limitations of the claims since it is not *hydrated* alumina. The obviousness rationale fails to provide any motivation for practicing the claimed invention and indeed proceeds contrary to the express teachings of Mehkeri.

Based on the foregoing, the Office Action fails to set forth a prima facie showing of obviousness under 35 U.S.C. § 103 over Mehkeri in view of the specification page 5, lines 7-8. Although Applicant disagrees that a prima facie case of obviousness has been established, the following evidence of unexpected results further establishes the patentability of the claimed invention.

Unexpected Results

“When evidence of secondary considerations such as unexpected results is initially before the Office, for example in the specification, that evidence should be considered in deciding whether there is a prima facie case of obviousness.” M.P.E.P. § 2144.08. “Evidence of unexpected results must be weighed against evidence supporting prima facie obviousness in making a final determination of the obviousness of the claimed invention.” M.P.E.P. § 716.02(c).I (*quoting In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978)). “[E]ach piece of rebuttal evidence should not be evaluated for its ability to knockdown a prima facie case. All of the competent rebuttal evidence taken as a whole should be weighed against the evidence supporting the prima facie case.” M.P.E.P. § 706.01(d) (*citing In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984)). As discussed above, the Office Action fails to even set forth a prima facie case of obviousness in view of the asserted prior art. Accordingly, such a weak initial showing of obviousness fails to render the claims unpatentable, particularly in view of the following evidence of unexpected results.

Particle Sizes in the Range of About 0.5 mm to about 1.5 mm

The pending claims require, *inter alia*, removal of *Cryptosporidium* from water comprising the steps of contacting the water with a medium consisting essentially of particulate

alumina having a diameter in the range of about 0.5 mm to about 1.5 mm. The specification discusses the importance of a medium size particles in maximizing collision and capture of biological species by the particles. Specification, page 6, first paragraph.

As discussed above, the examiner recognizes that a person of ordinary skill in the art would want to decrease rather than increase particle sizes in order to increase surface area. However, the Declaration Under 37 C.F.R. § 1.132 of Heriberto Alejandro Bustamante dated February 7, 2006 (“Bustamante Declaration I”) shows that medium size particles (0.5 to 1 mm) unexpectedly provide reasonable removal of oocyst using gravity alone compared to larger particles (2 to 4 mm). Specifically, oocysts were reduced in pilot plant operation by 2.5 to 3.5 logs when using hydrated alumina compared to 0.6 log reduction when using medium sized sand particles. In addition, tests carried out using large particle size hydrated alumina (2 to 4 mm) resulted in less than 10% removal of *Cryptosporidium* oocysts, which is less than a 0.05 log reduction. Appendix B, Bustamante Declaration I, ¶ 23; Appendix C, ¶ 15. This data demonstrates that large particle size hydrated alumina (2 to 4 mm), while suitable for gravity filtration, only removed 10% of the oocysts, while medium size particles of hydrated alumina (0.5 to 1 mm) attained unexpected levels of oocyst removal in the range of 2.5 to 3.5 log reduction while still being capable of gravity filtration. Thus, the medium sized particles of hydrated alumina showed an unexpected ability to adsorb *Cryptosporidium* oocysts.

Furthermore, the Declaration Under 37 C.F.R. § 1.132 of Heriberto Alejandro Bustamante dated September 28, 2006 (“Bustamante Declaration II”) shows that a person of ordinary skill in the art might have estimated that large particle size hydrated alumina would have had sufficient area to adsorb more than 20 million oocysts, but that testing demonstrated that the large particle size alumina was ineffective for oocyst removal in a pilot plant. The specification recognized that 0.5-2 mm particle sizes of hydrated alumina maximize the collision and capture of biological species by the particles. Specification, page 6, first paragraph. Thus, even if the person of ordinary skill in the art would have attempted to increase the size of the particles used in Mehkeri (which Applicant contests), he would have thought that large particle sizes have sufficient area to provide significant reductions in *Cryptosporidium* oocysts levels in contaminated water--but he would have been wrong. Applicant has thus demonstrated that the claimed range of particle sizes for hydrated alumina show unexpected results in terms of

maximizing the collision and capture of biological species by the particles. Accordingly, evidence of unexpected results demonstrates the nonobviousness of the pending claims under 35 U.S.C. § 103 in view of Mehkeri.

The Examiner discounts evidence of unexpected results stating that (1) the claims are not commensurate in scope with the showing of unexpected results, and (2) the unexpected property associated with alumina particles having a particle size between 0.5 and 1 mm has not been disclosed in the application as originally filed.

First the claims are commensurate in scope with the showing of unexpected results. The data in the Bustamante Declaration I shows that medium size particles outperform large size particles and the claims now state “a medium consisting essentially of particulate alumina having a diameter in the range of about 0.5 mm to about 1.5 mm.” The claims therefore would not encompass media having a sufficient number of large particles to lower the effectiveness of the filter. The Office Action fails to cite any prior art teaching a particulate alumina diameter anywhere near that which is claimed. Second, the specification discloses at page 6, line 2 that medium size particles up to the limits of the small and large particles respectively are preferred. Accordingly, the Office Action fails to establish why the evidence submitted by Application should be disregarded in the determination of obviousness as it apparently has been.

Unexpected Removal of *Cryptosporidium* with Hydrated Alumina

Claims 1, 3-5, 8, and 29 require, *inter alia*, removal of *Cryptosporidium* from water comprising the steps of contacting the water with a medium consisting essentially of particulate alumina . . . which alumina contains surface Al-OH groups occurring at an average rate of 1 hydroxyl group per 0.25 nm² to 1 hydroxyl group per 0.18 nm² surface area. The largely irreversible adsorption of *Cryptosporidium* on surface hydrated alumina is described throughout the specification. See example II, pages 15-17 and Figs. 7 and 8, which compare retention of *Cryptosporidium* by hydrated alumina relative to silica. Fig. 7 shows that when water containing *Cryptosporidium* is passed through a filter, there is substantial *Cryptosporidium* in the permeate and subsequent rinses when the filter is made up of silica. In contrast, Fig. 8 shows that very little *Cryptosporidium* passes through the filter in the permeate and in subsequent washes when hydrated alumina is used. The Declaration Under 37 C.F.R. § 1.132 of Marilyn Karaman dated March 22, 2002 (“Karaman Declaration”) compares the ability of hydrated alumina to retain

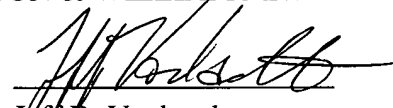
Cryptosporidium relative to a number of other inorganic solids, including silica. See Karaman Declaration, paragraphs 5-6 and Annex B, Fig. 1. In Figure 1, the Karaman Declaration shows that nearly 100% of the oocysts were eluted after a single washing in a silica column, while less than 20% of the oocysts were eluted after seven washings of a hydroxylated alumina column. The evidence in the specification and Karaman Declaration both show that hydrated alumina significantly outperforms silica in trapping *Cryptosporidium*. In contrast, Mehkeri fails to recognize any specific advantages of selecting alumina relative to silica or silica based media such as fuller's earth, diatomaceous earth, and CELITE. Moreover, Mehkeri fails to distinguish between hydrated alumina and alumina that is not hydrated. The obviousness rejection of record is clearly not sustainable in view of the foregoing evidence indicating the unexpected property of hydrated alumina being capable of enhanced adsorption of *Cryptosporidium* oocysts. Accordingly, the rejection of claims 1, 3-5, 8, and 27-29 under 35 U.S.C. § 103 as being obvious over Mehkeri in view of the specification page 5, lines 7-8 should be withdrawn.

Conclusion

The pending claims are nonobvious over Mehkeri in view of the specification page 5, lines 7-8 under 35 U.S.C. § 103 for all the foregoing reasons. Applicant submits that this response addresses all of the issues raised in the Office Action and places the pending claims in condition for allowance. Should any issues remain to be discussed in this application, the undersigned may be reached by telephone. In the event any variance exists between the amount authorized to be charged to the Deposit Account and the Patent Office charges for reconsideration of this application, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,
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